DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-788/S-003

Merck & Company, Inc.
Attention: Michael D. Rozycki, Ph.D.
Associate Director, Regulatory Affairs
Sumney town Pike
P.O. Box 4, BLA-20
West Point, Pennsylvania 19486-0004

Dear Dr. Rozycki:

Please refer to your new supplemental drug application dated January 28, 1999, received January 28, 9, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Propecia (finasteride) Tablets, 1 mg.

We acknowledge receipt of your submissions dated January 28, March 7 and June 14, 2000 and March 23, 2001.

This supplemental new drug application provides the addition of negative efficacy results in the labeling to further discourage women from using finasteride.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 20-788/S-003." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Millie Wright, Project Manager, at (301) 827-2020.

Sincerely,

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jonathan Wilkin

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